CALAMINE - ferric oxide red lotion
Vi Jon, LLC

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

Swan 063.001 063AA

Active ingredents

Calamine 8%

Zinc oxide 8%

Purpose

Skin Protectant

Use

dries the oozing and weeping of poison:•ivy • oak • sumac

Warnings

For external use only

When using this product

Do not get into eyes

Stop use and ask a doctor if

- condition worsens
- symptoms last more than 7 days or clear up and occur again within a few days

Keep out of reach of children

If swallowed, get medical help or contact a Poison Control Center right away

Directions

- shake well before using
- apply as needed

Other information

store at 59º - 86º F

Inactive ingredients

bentonite magma, calcium hydroxide, glycerin, purified water

adverse reactions

Vi-Jon, LLC

One Swan Drive

Smyrna, TN 37167

063.001/063AA

Principal display panel

NDC 0869-0063-30

SWAN

Calamine

Lotion

- Calamine topical Suspension USP
- Skin Protectant
- Poison Ivy, Oak, Sumac Drying Lotion

6 FL OZ (177 mL)

CALAMINE

ferric oxide red lotion

Product Information			
Product Type	HUMAN OTC DRUG	**Item Code (Source)**	NDC:0869-0063
Route of Administration	TOPICAL		

Active Ingredient/Active Moiety		
Ingredient Name	**Basis of Strength**	**Strength**
FERRIC OXIDE RED (UNII: 1K09F3G675) (FERRIC OXIDE RED - UNII:1K09F3G675)	FERRIC OXIDE RED	80 mg in 1 mL
ZINC OXIDE (UNII: SOI2LOH54Z) (ZINC OXIDE - UNII:SOI2LOH54Z)	ZINC OXIDE	80 mg in 1 mL

Inactive Ingredients	
Ingredient Name	**Strength**
BENTONITE (UNII: A3N5ZCN45C)	
CALCIUM HYDROXIDE (UNII: PF5DZW74VN)	
GLYCERIN (UNII: PDC6A3C0OX)	
WATER (UNII: 059QF0KO0R)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0869-0063-30	177 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1998	
2	NDC:0869-0063-26	118 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1998	
3	NDC:0869-0063-34	237 mL in 1 BOTTLE, PLASTIC; Type 0: Not a Combination Product	07/15/1998	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC monograph final	part347	07/15/1989	

Labeler - Vi Jon, LLC (790752542)

Registrant - Vi Jon, LLC (790752542)

Establishment

Name	Address	ID/FEI	Business Operations
Vi Jon, LLC		790752542	manufacture(0869-0063)

Revised: 4/2021 Vi Jon, LLC